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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SLOBODYANSKY, ELIZABETH	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/905,173	SHORT ET AL.	
	Examiner	Art Unit	
	Elizabeth Slobodyansky, PhD	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-55 and 93-111* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-55 and 93-111* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 20, 2004 has been entered.

The amendment filed August 20, 2004 amending the specification to correct clerical errors, amending claims 42, 43, 55, 93-103 and adding claims 105-111 has been entered.

The Declaration under 37 CFR 1.132 by Dr. Short filed in an unexecuted form August 20, 2004 and in an executed form August 25, 2004 has been entered.

Claims 42-55 and 93-111 are pending and under consideration.

Claim Objections

Claim 49 is objected to because the incorrect status identifier is indicated. Status identifier "(previously amended)" is not a permissible status identifier.

Applicant is advised that should claim 104 be found allowable, claim 111 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both

cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 104 and claim 111 depend from claim 95 and recite the limitation "wherein the aminotransferase activity is a histidinol phosphate aminotransferase activity" and "wherein the aminotransferase activity comprises a histidinol phosphate aminotransferase activity", respectively.

Claim Rejections - 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42-55 and 93-104 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 42, 93 and 95 recite "a [nucleotide] sequence comprising at least 30 consecutive nucleotides of a sequence encoding a polypeptide". While the specification provides support for fragments comprising 30 consecutive nucleotides of a single nucleotide sequence such as SEQ ID NO:23, the examiner is unable to locate adequate support for a nucleotide sequence comprising 30 consecutive nucleotides of any sequence encoding a polypeptide of SEQ ID NO:31. Thus there is no indication that fragments comprising 30 consecutive nucleotides of any sequence encoding a

polypeptide of SEQ ID NO:31 were within the scope of the invention as conceived by Applicants at the time the application was filed.

Accordingly, Applicants are required to cancel the new matter in the response to this Office Action.

Claims not specifically discussed above are rejected as dependent from the rejected base claim.

Claims 42-55 and 93-111 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 42 and 105 are drawn to a method of generating a variant nucleic acid encoding a polypeptide having an aminotransferase activity comprising modifying, deleting or adding one or more nucleotides in a nucleic acid encoding SEQ ID NO:31, SEQ ID NO:23 and sequences complementary thereto. Claims 93 and 95 drawn to a method of generating a variant nucleic acid encoding a polypeptide having an aminotransferase activity comprising modifying, deleting or adding one or more nucleotides in a nucleic acid encoding an aminotransferase activity and having at least 70% identity to SEQ ID NO:31, 70% identity to SEQ ID NO:23 or sequences complementary thereto. Since the number of possible modifications is not limited, the claims are drawn to a method of generating a variant nucleic acid of an unknown structure encoding an aminotransferase, any aminotransferase. Claims 96-103 depend

from claim 95 and limit the percent of the sequence identity to 75%, 80%, 90%, 95%, 96%, 97%, 98% and 99%, respectively. Claims 106 and 107 depending from claim 42, claims 108 and 109 depending from claim 93 and claims 110 and 104, 111 depending from claim 95 are limiting the aminotransferase activity to transferring of an amino group from -amino to -keto acid and to a histidinol phosphate aminotransferase activity, respectively. Thus, this part of the claims is directed to a method for generating a genus of nucleic acid molecules encoding any aminotransferase or histidinol phosphate aminotransferase from any source both naturally-occurring and man made having any structure because the number of allowed modifications is not limited. The specification teaches the structure of only a single representative species of such nucleic acids, SEQ ID NO:23. A generated variant of SEQ ID NO:23 is not required to have any identity with SEQ ID NO:23 but only to encode an aminotransferase activity . Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of encoding an aminotransferase.

Claim 42 further recites sequences comprising 30 consecutive nucleotides of a nucleic acid encoding SEQ ID NO:31, SEQ ID NO:23, or sequences complementary thereto. 30 nucleotides represent about 3% of the structure of SEQ ID NO:23 that is 1065 nucleotides long encoding 354 amino acids of SEQ ID NO:31. The recited structural feature of the genus (i.e., comprise a fragment of 30 nucleotides of SEQ ID NO:23 or a sequence encoding SEQ ID NO:31) does not constitute a substantial potion of the genus as the remainder of the structure of a polypeptide with aminotransferase

activity is completely undefined. Fragments consisting of 30 nucleotides of SEQ ID NO:23 are highly unlikely to encode aminotransferase activity and the specification does not define the remaining structural features necessary for members of the genus to be selected.

Claims 93 and 95 recite sequences comprising 30 consecutive nucleotides of a nucleic acid encoding an aminotransferase activity and having 70% identity to SEQ ID NO:31, or 70% identity to SEQ ID NO:23, or sequences complementary thereto. Similarly, the issues discussed in the preceding paragraph are applicable hereto.

Furthermore, the term aminotransferase encompasses a diverse class of enzymes having different substrate and stereo specificity with regard to the amino group donor and acceptor.

The specification does not disclose identifying characteristics which would allow to distinguish an aminotransferase of a defined donor-acceptor and stereo specificity such as a histidinol phosphate transaminase, for example, from another aminotransferase specific for a different donor-acceptor pair.

The specification teaches the structure of only a single representative species of such nucleic acids, i.e., that of SEQ ID NO:23 encoding histidinol phosphate aminotransferase (page 74). Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties and/or fails to describe the correlation between structure and function common to all members of the genus. Given this lack of description of representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention

in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims not specifically discussed in this rejection are rejected as dependent from a rejected base claim.

Claims 42-55 and 93-111 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of generating a variant nucleic acid sequence encoding a histidinol phosphate transaminase comprising creating a library of variants of SEQ ID NO: 23 or a sequence encoding SEQ ID NO:31 by modifying (i.e., adding, deleting or substituting) one or more nucleotides of SEQ ID NO: 23, expressing said modified sequences, screening the proteins produced from said modified sequences for a histidinol phosphate aminotransferase activity and selecting a variant sequence which encodes a protein having a histidinol phosphate aminotransferase activity, does not reasonably provide enablement for methods of generating variants of SEQ ID NO:23 encoding an aminotransferase, i.e. any aminotransferase as well as encoding a histidinol phosphate transaminase absent the screening step for an the activity and does not reasonably provide enablement for methods of generating a variant nucleic acid sequence encoding histidinol phosphate transaminase by modifying sequences that are at least 70% identical to SEQ ID NO;23 or nucleic acid sequences encoding a polypeptide at least 70% identical to SEQ ID NO: 31 or by modifying sequences that comprise at least 30 nucleotides of the SEQ ID

NO:23, a sequence encoding SEQ ID NO: 31 and homologous sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 42-55 and 95-111 are so broad as to encompass methods for generating any variant of SEQ ID NO:23 encoding any aminotransferase, said methods having no step of screening for the aminotransferase activity, including histidinol phosphate transaminase activity. Therefore, one of ordinary skill in the art must know where exactly in the sequence and which changes to make in order for the encoded polypeptide to retain the histidinol phosphate transaminase activity or to switch said activity to another aminotransferase activity. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of methods broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. While recombinant and mutagenesis techniques are known, the number of modifications that can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled

in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions. As such the skilled artisan would not expect the claimed methods to result in a variant encoding a polypeptide having any aminotransferase activity at all, including histidinol phosphate transaminase activity, absent a step of screening a group of variant sequences for those which encode proteins which have the defined aminotransfrerase activity.

Furthermore, the claims are drawn to methods for generating a variant nucleic acid encoding an aminotransferase starting with a sequence that is not SEQ ID NO:23 and has a defined homology thereto such as at least 70% or comprises at least 30 nucleotides of a sequence and has no defined homology to SEQ ID NO: 23.

While claim 95 and claims dependent thereon comprise the step of screening, they are included in this rejection because a) the starting sequence is not SEQ ID NO:23 and b) the aminotransferase activity is not limited to histidinol phosphate transaminase activity.

The specification does not support the broad scope of the claims which encompass methods of generating variants of the nucleic acids of SEQ ID NO:23 or encoding SEQ ID NO:31 or variants thereof and having a transaminase activity because one of skill in the art would not know how to use the vast majority of the products of the claimed methods as the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting an aminotransferase activity, including histidinol phosphate transaminase activity; (B) the general tolerance of aminotransferase genes including histidinol phosphate transaminase genes, to

modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including methods of making any variant of SEQ ID NO:23 or encoding SEQ ID NO:31 as the specification does not teach what one would use the vast numbers of variants which encode proteins lacking any aminotransferase activity and it is not predictable which modifications will lead to variants encoding an active aminotransferase and what substrate and/or stereo specificity said aminotransferase will exhibit. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of methods leading to genes having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43, 55, 94-104 and 106-111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 43, 55 and 94 recite trademarks. The metes and bounds of these terms are unclear. It is unclear what kind of limitation the trademark imposes on the process.

Claims 96-103, 110 and 111 depend from claim 95 that on several occasions recites "a polypeptide". Therefore, it is unclear to which of these polypeptides the limitation "wherein the polypeptide having an amino transferase activity" is related. Claim 95 recites "an aminotransferase activity" on several occasions. Therefore, it is unclear to which of these occasions the limitation "wherein the aminotransferase activity is a histidinol phosphate aminotransferase activity" in the dependent claim 104 is related.

Claims 106-111 recite "wherein the aminotransferase activity comprises catalyzing the transfer ...". The use of "comprises" renders the claims confusing because it is unclear whether additional aminotransferase activities are encompassed.

Response to Amendment

The Declaration under 37 CFR 1.132 by Dr. Jay Short filed August 20, 2004 is insufficient to overcome the enablement rejection as set forth in the last Office action because of the following.

Dr. Short states that "at the time of the invention, aligning nucleic acid or polypeptide sequences was a routine method for comparing sequences to identify

common structural characteristics (e.g., sequences, motifs) related to a function such as aminotransferase activity. One skilled in the art could have aligned and compared the disclosed exemplary sequences of the invention to each other or to known transaminase sequences to determine common, specific structural characteristics reasonably related to the genus of transaminases used in the claimed methods, e.g., as illustrated in Exhibit A. Exhibit A shows a sequence alignment among SEQ ID Nos 23 and 31, relevant to the claims in this application, and several other aminotransferase disclosed in this application" (Declaration, page 1). This is not persuasive because the rejection is made not because the alignment cannot be done but because the additional information is needed in order to practice the claimed methods. It is noted that the aligning of the enzymes of different strictures and functions shown in Exhibit A does not provide a guidance as to where and which changes in the nucleotide sequence should be made in order to retain the activity of SEQ ID NO:31 or to switch it to other aminotransferase activities. Dr. Short further states that "screening assays were known in the art at the time of the invention" (pages 2-3). While the screening assays were known for numerous activities, the specification provides no guidance as to for which activity the variant should be screened. Furthermore, some claims do not have the screening step at all. Dr. Short further states that "Procedures for determining sequence identity to an exemplary nucleic acid were routine in the art at the time of the invention. Procedures for expressing and screening for transaminase activity were conventional and routine in the art at the time of the invention. One of ordinary skill in the art using the teaching of the specification would have been able to make and use the genus of

compositions used in the methods of the invention, including a genus of transaminase-encoding nucleic acids having at least 70% sequence identity to the exemplary nucleic acid without undue experimentation. It was considered routine by one skilled in the art at the time of the invention to screen for multiple substitutions or modifications of a nucleic acid or a polypeptide for functional variations including screening for a genus of transaminase-encoding nucleic acids or a genus of transaminases" (page 4). This is not persuasive because these arguments are not responsive to the problems identified in the rejection. While the method of obtaining the sequence that is highly homologous to SEQ ID NO:23 and encodes the same histidinol phosphate transaminase activity may be enabled, the current claims are drawn to a method of obtaining a polypeptide of any structure having no defined homology to SEQ ID NO:23 and having any undefined aminotransferase activity.

Response to Arguments

Applicant's arguments filed August 20, 2004 have been fully considered but they are not persuasive.

With regard to the election of Group IV, claims 42-55 and a polynucleotide encoding SEQ ID NO:31, with traverse made March 25, 2003 (Paper No. 14), Applicants argue that the Patent Office should reconsider and allow the rejoinder of nucleotide groups A, B, C, D, F, and J, all transaminases originally derived from the organism *Aquifex* (Remarks, page 12). This is incorrect because some sequences

derived from *Ammonifex* and *Pyrobacullum*. Additional arguments are given in the Office action mailed June 17, 2003.

With regard to the 112, 1st paragraph, written description rejection, Applicants argue that "amended claims 93 and 95 are now directed to methods using nucleic acids comprising sequences having at lest 70% sequence identity to a sequence as set forth in SEQ ID NO:23, or a nucleic acid encoding an amino acid sequence as set forth in SEQ ID NO:31, and their complementary sequences" (page 14). Applicants continue "because the *starting products* of the methods are adequately described, the specification satisfies the written description requirement of section 112" (ibid). This is not persuasive because the starting products are not necessarily sufficiently described since they encompass polypeptides having any aminotransferase activity that are encoded by nucleotide sequences comprising 30 nucleotides. More importantly, the claimed methods are methods of making a product that is insufficiently described because it is described at most by function only. The method of making the product should describe the product. Applicants further argue that "the genus has been described in terms of structure (the exemplary nucleic acid SEQ ID NO:23, or encoding SEQ ID NO:31) and physico-chemical properties (e.g., percent sequence identity) in addition to function (e.g., encoding polypeptides having transaminase activity)" (ibid). This is not persuasive because percent identity is structural not physico-chemical property and transaminase activity comprises a great number of activities. Applicants further argue that "As discussed in Applicants' previous response, Example 14 of the Guidelines concluded that a claim reciting variants claimed by sequence identity to a

sequence is sought (specifically, A protein having SEQ ID NO:3 and variants thereof that are at least 95% identical to SEQ ID NO:3 and catalyze the reaction of A-B) satisfies the written description requirement of section 112, first paragraph" (page 15). This is not persuasive because the example in the Guidelines is different from the instant case. First, the claimed variants must be 95% identical to the sequence of the protein that exhibits the requisite catalytic activity. Therefore, said variants are described by structure. In the instant case, as explained above, the claimed polypeptide may have a very low or no homology to a protein exhibiting catalytic activity. Therefore, in the instant case there are insufficient structural limitations. Second, in the example the activity is known. Instead, in the instant case, the reaction that is catalyzed is unknown because transaminases catalyze numerous different reactions.

Applicants further discuss Dr. Short's Declaration (pages 15-17). The issues raised in the Declaration have been discussed above. Applicants discussed Dr. Short's Declaration to argue the enablement rejection. In addition to what have been discussed above, Applicants argue that the specification enabled the invention as claimed. Applicants refer to the declaration to argue that the state of the art at the time of the invention and the level of skill of the person of ordinary skill in the art was very high. Dr. Short s declaration further states that one of skill in the art at the time of the invention could use the teachings of the specification and other protocols known in the art to screen for nucleic acids encoding polypeptides having aminotransferase activity and that while the number of samples needed to be screened may have been high, the screening procedures were routine and successful results predictable. According to Dr.

Short s declaration, knowledge of the specific structural elements which correlate with aminotransferase activity would not have been required to create variants and test them for activity. Applicants further argue that enablement is not precluded by the necessity to screen large number of compositions as long as that screening is routine. Applicants refer to *Hybritech, Inc. v. Monoclonal Antibodies, Inc.* as support for the argument that the claimed invention is enabled even if there is a need to screen large numbers of negatives to find a sample with the desired activity.

As indicated above, the specification is completely silent in regard to which are the amino acid residues which can be substituted, deleted, or inserted in the nucleic acid of SEQ ID NO:23 to obtain structural homologs of the nucleic acid of SEQ ID NO:23 as recited in the claims which encode proteins with aminotransferase activity. In addition, the specification does not provide any guidance as to which 30 consecutive base fragments of the nucleic acid of SEQ ID NO: 23 or another nucleic acid sequence encoding SEQ ID NO;31 are required to encode proteins with aminotransferase activity nor does it provide any guidance as to which fragments of a nucleic acid having at least 70% sequence identity to the SEQ ID NO: 23 or 31 and encoding an aminotransferase are essential for aminotransferase activity. The prior art clearly teaches the unpredictability of assigning function based on structural homology and how small structural changes can lead to major changes in function. For specific teachings of such unpredictability, see Bork, Broun et al., Van de Loo et al., Witkowski et al. and Seffernick et al. Each of these references which are presented merely as evidence of the state of the art as previously characterized by the examiner, shows that even small

changes in the primary structure of an encoded protein can have substantial effects on function. Furthermore, it should be noted that applicants claims encompass the use of not only nucleic acids having minor changes in structure from SEQ ID NO: 23 or encoding SEQ IDNO:31, but include nucleic acids with major changes as well. Therefore, in the absence of any information as to how structure correlates with function, one of skill in the art would have to go through the burden of undue experimentation to isolate/make the nucleic acids as encompassed by the claims, to practice the full scope of the claimed invention.

The declaration of Dr. Short state that methods of making variants of a known sequence are well known in the art, including methods which result in more than one change in a sequence and that the skilled artisan is capable of screening any specific sequence to determine if it has activity. This is not disputed by the examiner. However, applicants arguments amount to a conclusion that screening for any aminotransferase should be enabled because the artisan knows how to look for it, can identify it when it is seen and knows it is there somewhere. This is not case. It is well established that while enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the **specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.** The only guidance present in the specification for selecting the generated aminotransferase is the sequences of SEQ ID NOs:23 and 31 themselves. This is clearly insufficient given that the claims require no structural homology to these sequences to be maintained (i.e., the genus is enormous) and the known fact that only

a very minuscule portion of the sequences having claimed structural features will have aminotransferase activity.

The previous 112, 2nd paragraph, rejection is moot in view of the amendment.

The 102(b) and 103 rejections are withdrawn in view of the amendment. ,

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner
Art Unit 1652

November 5, 2004